

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Adverse kidney effects of standard -daily dosing versus once daily dosing of amikacin among preterm neonates

Protocol summary

Summary

The aim of this study is to compare the renal damage caused by standard and once daily dose of Amikacin in premature infants with suspected sepsis. According to formula, the sample volume will be 40 infants. This study will be carried out in "Shahid Akbar Abadi" Hospital. Inclusion criteria: Preterm infants with normal intrauterine growth and sepsis suspicion at birth. Exclusion criteria: Neonate who received incomplete treatment; Parents dissatisfaction for continuation of treatment; asphyxia; renal anomalies in ultrasound after birth. Preterm neonates with sepsis diagnosis will be divided to two groups (A and B) randomly. One group of neonates will receive standard dose of Amikacin and the other one, single daily dose. All of them will also receive 100 mg / kg / d Ampicillin each 8 or 12- hour. Before initializing the treatment, CBC, diff, blood culture, BUN, creatinine and urinary N-GAL will be checked. To rule out renal anomalies in infants during the first week after birth, ultrasound of the kidneys and urinary tract will be done. CBC, diff, BUN and creatinine will be rechecked on the third and fifth days of the treatment. In both groups, maximum and minimum of Amikacin serum level will be checked. The maximum Amikacin serum level will be reached 30 minutes after injection. With this sample the level of creatinine in the blood will also be checked. To determine the minimum level of Amikacin serum, sampling is done 30 minutes before the first injection of Amikacin on the fifth day. With this sample serum creatinine level is also measured. Urinary NGAL levels will be measured on the seventh day. Sampling will continue to the seventh day of treatment and until the number of children who have urinary N-GAL levels in each group (A and B) reaches 20. To study the adverse effects of Amikacin on kidneys, serum creatinine level and urinary N-GAL will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015103124804N1**

Registration date: **2016-02-05, 1394/11/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-05, 1394/11/16

Registrant information

Name

Arash Bordbar

Name of organization / entity

Iran university of medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2296 9030

Email address

bordbar.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Adverse kidney effects of standard -daily dosing versus once daily dosing of amikacin among preterm neonates

Public title

Adverse effects of amikacin on preterm infants kidneys

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Appropriate for gestational age preterm infants with early onset sepsis diagnosis Exclusion criteria:neonates with incomplete treatment ; whom their parents do not accept to be included in this trial ; asphyxia; kidney anomalies in ultrasonography

Age

To **7 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Tehran, Iran

City

Tehran

Postal code

Approval date

2015-09-01, 1394/06/10

Ethics committee reference number

IR.IUMS.REC.1394.9111165005

Health conditions studied

1

Description of health condition studied

Bacterial sepsis of newborn

ICD-10 code

P36

ICD-10 code description

Bacterial sepsis of newborn

Primary outcomes

1

Description

Urinary NGAL rising

Timepoint

at admission before initialling amikacin and at 7th day after completing treatment

Method of measurement

Using Urinary NGAL kit

Secondary outcomes

1

Description

serum cr & BUN rising

Timepoint

at admission and 3th, 5th and 7th day

Method of measurement

by blood sampling

Intervention groups

1

Description

Amikacin administration as once daily dose intravenously for 7 days

Category

Treatment - Drugs

2

Description

Amikacin administration as standard daily dose intravenously for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi Hospital

Full name of responsible person

Dr Arash Bordbar

Street address

Shahid Akbarabadi Hospital, Mowlavi st, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Seyyed Ali Javad Mousavi

Street address

Iran University of Medical Sciences, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Arash Bordbar

Position

Neonatologist/ Professor Assistant

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty